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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/015,536	12/10/2001	David M. Kranz	103-00	9971

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EXAMINER
EPPERSON, JON D

ART UNIT	PAPER NUMBER
1639	7

DATE MAILED: 06/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/015,536	Applicant(s) KRANZ ET AL.	
	Examiner Jon D Epperson	Art Unit 1639	

Ref Copy

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-25* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Please note: The Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to **Group Art Unit 1639**.

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-10, drawn to a product described as a mutangenized combinatorial library of Major Histocompatibility Complex (MHC) Class II chimeric proteins displayed on the surfaces of recombinant yeast cells, classified variously in class 435, subclass 7.1, DIG 27.

II. Claims 11-17, drawn to a product described as an isolated mutant MHC Class II chimeric protein, classified variously in class 530, subclass 350+; class 424, subclass 192.1.

III. Claims 18-21, drawn to a method for detection of a lymphocyte having a T cell receptor protein in a biological sample, classified variously in class 435, subclass 4, 7.1.

IV. Claims 22-25, drawn to a method for activating or enhancing an immune response to an abnormal cell, classified variously in class 435, subclass 9.2, FOR 184.

2. The inventions are distinct, each from the other because of the following reasons:

3. For example, Groups I-II represent patentably distinct products. Groups I-II represent separate and patentably distinct products because they differ in respect to their properties, their use and the synthetic methodology for making them. For example, Group I is drawn to a library, whereas Group II is drawn to single compound. Different reagents and materials are required to produce a library and a library is also used for a different purpose than a single compound. Therefore, art anticipating or rendering obvious each Group would not render obvious the other Group, because they are drawn to different inventions that have different distinguishing features and/or characteristics. Consequently, Groups I-II have different issues regarding patentability and enablement and represent patentably distinct subject matter.

4. Groups III-IV represent separate and patentably distinct methods. The methods are distinct because they use different steps, require different reagents and/or will produce different results. For example, Group IV requires method steps and reagents (including animals and/or humans) for "enhancing an immune response", which are reagents and/or method steps that are not required by the method of Groups III. Therefore, each method recites distinct procedural steps, using distinct compositions and with each method directed to a different outcome. A search of each method would not be co-extensive with a search of the others and hence would be burdensome. Each method is capable of supporting its own patent.

5. Finally, Groups I-IV represent separate and distinct inventions because Group III-IV claim methods while Group I-II claim products. However, if applicant were to argue that Groups II-IV were somehow related as product and process of use, the inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as

claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the product(s) as claimed (i.e., Groups II) can be used in materially different process of using that product (MPEP § 806.05(h)), for example, the products could be used in the method of Group III or Group IV.

6. These inventions have acquired a separate status in the art as shown by their different classification and/or divergent subject matter. The different methods and products would require completely different searches in both the patent and non-patent databases, and there is no expectation that the searches would be coextensive. Therefore, this does create an undue search burden, and restriction for examination purposes as indicated is proper.

7. This application contains claims directed to patentably distinct species of the claimed invention for Groups I-IV. Election is required as follows.

8. If applicant elects the invention of Group I, applicant is required to elect from the following patentably distinct species. Claim 1 is generic.

Subgroup 1: Species of MHC Class II chimeric proteins (see claim 1)

Applicant must elect, for the purposes of search, a ***single species*** of Class II chimeric proteins. Applicants must specify **ALL** portions of the protein including the signal sequence, peptide (e.g., SEQ ID NO: 19, see claim 15), Linker1 (e.g., $Gly_2ProGly_3SerGly_3$), peptide binding region, Linker2 (e.g., $Gly_2IleGlySer(Gly_4Ser)_2$), tag (e.g., c-myc) and adaptor protein (e.g., AGA2, see claim 4) and any "detectable label" if present (Note Applicant must indicate if it is a fluorescent label, etc., see claim 17, and

provide the chemical structure for the label). Applicants must also provide the amino acid sequence (e.g., SEQ ID NO:17, see claim 10). Please note that the elected species should be a "representative" structure of the compounds in the library that contains a ***particularly defined*** core structure that is shared by all library members.

Subgroup 2: Species of mutation (see claim 1)

Applicant must elect, for the purposes of search, a ***single species*** of mutation e.g., applicant must show where and how the chimeric protein from subgroup 1 was mutated i.e., Applicants must indicate the EXACT position at which the mutation occurs.

Subgroup 3: Species of autoimmune disease (see claim 8)

Applicant must elect, for the purposes of search, a ***single species*** of target cell e.g., insulin dependent diabetes mellitus.

9. If applicant elects the invention of Group II, applicant is required to elect from the following patentably distinct species. Claim 11 is generic.

Subgroup 1: Species of MHC Class II chimeric proteins (see claim 11)

Applicant must elect, for the purposes of search, a ***single species*** of Class II chimeric proteins. Applicants must specify **ALL** portions of the protein including the signal sequence, peptide (e.g., SEQ ID NO: 19, see claim 15), Linker1 (e.g., $Gly_2ProGly_3SerGly_3$), peptide binding region, Linker2 (e.g., $Gly_2IleGlySer(Gly_4Ser)_2$), tag (e.g., c-myc) and adaptor protein (e.g., AGA2) and any "detectable label" if present. Applicants must also provide the amino acid sequence (e.g., SEQ ID NO:17).

Subgroup 2: Species of mutation (see claim 11)

Applicant must elect, for the purposes of search, a ***single species*** of mutation e.g., applicant must show where and how the chimeric protein from subgroup 1 was mutated i.e., Applicants must indicate the EXACT position at which the mutation occurs.

Subgroup 3: Species of autoimmune disease (see claim 14)

Applicant must elect, for the purposes of search, a ***single species*** of target cell e.g., insulin dependent diabetes mellitus.

Subgroup 4: Species of detectable label (see claim 17)

Applicant must elect, for the purposes of search, a ***single species*** of detectable label (e.g., fluorescent). Furthermore, applicant must show ***all*** atoms and bonds that are necessary to define said compound of general formula I. Applicant should NOT use general notations like R^1, R^2, etc. when defining the structure because these labels represent more than one chemical group and thus more than one compound would be erroneously elected.

10. If applicant elects the invention of Group III, applicant is required to elect from the following patentably distinct species. Claim 18 is generic.

Subgroup 1: Species of MHC Class II chimeric proteins (see claim 18)

Applicant must elect, for the purposes of search, a ***single species*** of Class II chimeric proteins. Applicants must specify **ALL** portions of the protein including the signal sequence, peptide (e.g., SEQ ID NO: 19), Linker1 (e.g., $Gly_2ProGly_3SerGly_3$), peptide binding region, Linker2 (e.g., $Gly_2IleGlySer(Gly_4Ser)_2$), tag (e.g., c-myc) and adaptor protein (e.g., AGA2) and any "detectable label" if present. Applicants must also provide the amino acid sequence (e.g., SEQ ID NO:17).

Subgroup 2: Species of mutation (see claim 18)

Applicant must elect, for the purposes of search, a ***single species*** of mutation e.g., applicant must show where and how the chimeric protein from subgroup 1 was mutated i.e., Applicants must indicate the EXACT position at which the mutation occurs.

Subgroup 3: Species of biological sample (see claim 19)

Applicant must elect, for the purposes of search, a ***single species*** of biological sample (e.g., biopsy material).

Subgroup 4: Species of autoimmune disease (see claim 21)

Applicant must elect, for the purposes of search, a ***single species*** of target cell e.g., insulin dependent diabetes mellitus.

11. If applicant elects the invention of Group IV, applicant is required to elect from the following patentably distinct species. Claim 22 is generic.

Subgroup 1: Species of MHC Class II chimeric proteins (see claim 22)

Applicant must elect, for the purposes of search, a ***single species*** of Class II chimeric proteins. Applicants must specify **ALL** portions of the protein including the signal sequence, peptide (e.g., SEQ ID NO: 19, see claim 25), Linker1 (e.g., $Gly_2ProGly_3SerGly_3$), peptide binding region, Linker2 (e.g., $Gly_2IleGlySer(Gly_4Ser)_2$), tag (e.g., c-myc) and adaptor protein (e.g., AGA2) and any "detectable label" if present. Applicants must also provide the amino acid sequence (e.g., SEQ ID NO:17, see claim 24).

Subgroup 2: Species of mutation (see claim 22)

Applicant must elect, for the purposes of search, a ***single species*** of mutation e.g., applicant must show where and how the chimeric protein from subgroup 1 was mutated i.e., Applicants must indicate the EXACT position at which the mutation occurs.

Subgroup 3: Species of human or animal (see claim 22)

Applicant must elect, for the purposes of search, a ***single species*** of human or animal (e.g., human).

Subgroup 4: Species of administration (see claim 22)

Applicant must elect, for the purposes of search, a ***single species*** of administration (e.g., intravenous).

Subgroup 5: Species of autoimmune disease (see claim 22)

Applicant must elect, for the purposes of search, a ***single species*** of target cell e.g., insulin dependent diabetes mellitus.

12. **Please Note:** Applicants must disclose which claims read on the elected species (see paragraphs 16 and 17 below).

13. The species are distinct, each from the other, because their structures and modes of action are different. They would also differ in their reactivity and the starting materials from which

they are made. For different species of method, the method steps for each species would differ. Moreover, the above species can be separately classified. Consequently, the species have different issues regarding patentability and represent patentably distinct subject matter. Therefore, this does create an undue search burden, and election for examination purposes as indicated is proper.

14. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

15. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a a rejection under 35 U.S.C. 103(a) of the other invention.

16. Applicant is advised that a reply to this requirement ***must include an identification of the species that is elected consonant with this requirement***, ***and a listing of all claims readable thereon, including any claims subsequently added***. An argument that a claim is allowable or that all claims are generic is considered ***nonresponsive*** unless accompanied by an election.

17. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, ***applicant must indicate which are readable upon the elected species***. MPEP § 809.02(a).

18. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.43). Because the above restriction/election requirement is complex, a telephone call to applicants to request an oral election was not made. See MPEP § 812.01.

19. Applicant is reminded that upon cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

20. Applicant is also reminded that a 1 – month (not less than 30 days) shortened statutory period will be set for response when a written requirement is made without an action on the merits. This period may be extended under the provisions of 37 CFR 1.136(a). Such action will not be an "action on the merits" for purposes of the second action final program, see MPEP 809.02(a).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon D Epperson whose telephone number is (703) 308-2423. The examiner can normally be reached Monday through Friday from 8:30 a.m. to 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang, can be reached on (703) 306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-2439.

Jon D. Epperson, Ph.D.
June 1, 2003

BENNETT CELSA
PRIMARY EXAMINER